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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/937,730

01/08/2002

Mie Takahashi

2001-1464A

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7590

07/13/2004

WENDEROTH, LIND & PONACK, L.L.P.

2033 K STREET N. W.

SUITE 800

WASHINGTON, DC 20006-1021

EXAMINER

COUNTS, GARY W

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 07/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/937,730

Applicant(s)

TAKAHASHI ET AL.

Examiner

Gary W. Counts

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on January 8, 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 09/28/01, 01/08/02.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement filed September 28, 2001 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the copies of English translations of the foreign documents JP 3-120468, JP 3-120469, JP 3-120470 and JP 11-64336 . It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Foreign document JP 11-153601 has been considered because an explanation of its relevance was provided on page 3 of the specification. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

Specification

The disclosure is objected to because of the following informalities: The specification on page 7 under the section entitled "DISCLOSURE OF THE INVENTION" uses the phrase "according to claim 1". This practice is not conventional for U.S. Applications. (See also phrases directed toward other claims throughout the specification.

Appropriate correction is required.

Claim Objections

Claim 1 is objected to because of the following informalities: The term "wherein" in line 4 of claim 1 should be replaced with --comprising--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, line 1 the recitation "a chromatography specimen" is vague and indefinite. It is unclear if the specimen recited in the claims is meant as a sample or a device. The term specimen is conventionally meant as a sample. For example, Webster's II New Riverside University Dictionary defines specimen as "a sample, as of tissue, blood or urine used for analysis and medical diagnosis." However, the recitation "A chromatography specimen" reads like it should be a device or apparatus. Thus, one of ordinary skill in the art cannot determine the metes and bounds of "a chromatography specimen". Please clarify. See also deficiencies found in claims 2-63.

Claim 1, line 1 the recitation "is obtained by" is vague and indefinite. The term "is obtained by" is not a positive limitation to the chromatography specimen itself. Does applicant intend that the chromatography specimen comprises plural wettable porous material.

Claim 1, line 5 "reactive components" is vague and indefinite. It is unclear what the term encompasses. There is no definition provided for the term in the specification. See also deficiencies found in claim 8.

Claim 1, line 5 "adopted in" is vague and indefinite. It is unclear how the reactive components are adopted in a chromatographic analysis. Please clarify. See also deficiency found in claim 8.

Claim 1, line 7 "having such a property" is vague and indefinite. It is unclear what property applicant is referring to. See also deficiency found in claim 8.

Claim 1, line 7 the recitation "can be" is vague and indefinite. Does the surface active agent have a property that is solidified when dried or not? The recitation "can be" is not a positive limitation. It does not constitute a limitation in any patentable sense. See also deficiency found in claim 8.

Claim 1 is vague and indefinite because it is unclear if the immobilized reactive component or the reactive layer is solidified when dried.

Claim 2 is vague and indefinite because of the use of an acronym: i.e. HLB. Although the term may have art-recognized meanings, it is unclear if applicant intends to claim the prior art definitions. The term should be defined in its first instance. See also deficiency found in claim 9.

Claim 2 is vague and indefinite because it is unclear if the "surface active agent" comprises a second surface active agent or if the "surface active agent" has a HLB value which is 20 or lower. See also deficiency found in claim 9.

Claim 5 is vague and indefinite because it is unclear if the sugar has a hydrophilic part or if the chromatography specimen has a hydrophilic part which comprises a sugar. See also deficiency found in claim 12.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-3, 6-10, 13, 16-18, 24, 25, 28, 29, 32, 38, 39, 50, 57 and 58 are rejected under 35 U.S.C. 102(e) as being anticipated by Jobling et al (US 6,130,100) in light of Caridi (US 4,810,738).

Jobling et al disclose test strips and a process of manufacturing test strips (abstract and col 2, lines 31-67). Jobling et al disclose that the strip comprises a porous material which comprises a test zone (reactive layer) having immobilized specific binding reagents (reactive components) (col 2, lines 31-67 and col 3, lines 21-26). Jobling et al discloses that a solution comprising Tween 20 (surfactant, surface active agent) is applied to the porous strip and dried (col 6, lines 1-29). Jobling et al teaches that the drying step is performed by air drying. (col 6, lines 27-29). Jobling et al teaches that the solution migrates from one end of the strip to the other end (col 6 and

Figures 1-3b). Therefore, Jobling teaches the entire reactive layer is impregnated with the surface active agent.

Regarding claims 2, 3, 9 and 10 Jobling teaches that the surface active agent is Tween 20. Jobling fails to specifically state that Tween 20 is non-ionic and has a HLB value of 20 or below. Cardi teaches that Tween 20 is a non-ionic surface active agent and has an HLB value of 17. Therefore, Jobling et al teaches a non-ionic surface active agent having an HLB value which is 20 or lower.

5. Claims 1-4, 6-11, 13, 14, 16-20, 24-26, 28-30, 32-34, 38-40, 42-44, 50-52, 54, 55, 57-59, 61 and 62 are rejected under 35 U.S.C. 102(e) as being anticipated by Chu (US 6,284,194).

Chu discloses an analytical device and method of making the device. Chu teaches that the device comprises a porous reaction membrane and at least one receptor immobilized in a limited region (col 1, lines 40-50) (reaction layer and reactive components). Chu teaches applying a surfactant (surface active agent) to the reaction membrane and allowing to dry (col 1, lines 55-67). Chu teaches that drying can be performed by air drying at room temperature or by warm air with good ventilation (col 9, lines 30-43). Chu teaches that the surfactant (surface active agent) can be cholic acid surfactant (col 6, lines 25-26 and col 7, lines 44-67). Chu also teaches that the surfactant (surface active agent) can be a non-ionic surfactant such as Tween 20 (col 8, lines 2-20). Chu teaches that all or most of the surface (col 5, lines 27-32) is exposed to the surfactant.

Regarding claims 2, 3, 9 and 10 Chu teaches that the surface active agent can be Tween 20. Chu fails to specifically state that Tween 20 has a HLB value of 20 or below. Cardi teaches that Tween 20 is a non-ionic surface active agent and has an HLB value of 17. Therefore, Chu teaches a non-ionic surface active agent having an HLB value which is 20 or lower.

With respect to claims 14, 42-44, 55 and 62 as recited in the instant claims. Chu teaches that drying can be performed by warm air in good ventilation. Therefore, Chu teaches drying in moving air (wind) and thus Chu teaches wind drying as recited in the instant claims.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

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the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 5, 12, 21-23, 27, 31, 35-37, 41, 45, 53 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chu (US 6,284,194) in view of Yamamoto et al (US 6,117,289).

See above for teachings of Chu.

Chu differs from the instant invention in failing to teach the surface active agent comprises a surface active agent having sugar in a hydrophilic part.

Yamamoto et al disclose surfactants (surface active agent) used in bioassays. Yamamoto et al disclose that the surfactant (surface active agent) can be n-octyl-B-D-thioglucoside (sugar in hydrophilic part) or sucrose monolaurate (also contains sugar in hydrophilic part) (col 4, lines 11-17). Yamamoto et al disclose that this surfactant is added to a reaction layer and dried (col 3, lines 48-52). Yamamoto et al discloses this provides for a sensor that facilitates rapid and simplified quantitation of an analyte contained in sample with accuracy.

It would have been obvious to one of ordinary skill in the art to substitute the n-octyl-B-D-thioglucoside or sucrose monolaurate surfactants (surface active agent) as taught by Yamamoto et al for the surface active agent of Chu because Yamamoto et al

teaches that this provides for a sensor that facilitates rapid and simplified quantitation of an analyte contained in sample with accuracy. Further Chu teaches that polyethylene glycols are a preferred surfactant and Yamamoto teaches the equivalence of polyethylene glycol surfactants to n-octyl-B-D-thioglucoside or sucrose monolaurate surfactants (col 4, lines 11-17) for their addition to reaction layers (col 3) and the selection to any known equivalents to replace the surfactants of Chu would be within the level of ordinary skill in the art and one of ordinary skill in the art would have a reasonable expectation of success using the surfactants (surface active agents) of Yamamoto in the method and device of Chu.

10. Claims 15, 46-48, 56 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chu (US 6,284,194) in view of Iwata et al (Us 5,912,139).

See above for teachings of Chu.

Chu differs from the instant invention in failing to teach the reactive layer is dried by freeze drying.

Iwata et al disclose producing a test strip by impregnating a carrier with a solution comprising components. Iwata et al disclose that the impregnated carrier is then dried by freeze drying (col 6, lines 48-59). Iwata et al disclose that the components can be surfactants (col 6, lines 3-14 and col 10, lines 10-22). Iwata et al disclose that freeze drying thoroughly removes water from the carrier (col 6, line 53). Iwata et al disclose that this provides for a test strip, which provides high sensitivity and high accuracy measurement and excellent storage stability (abstract & col 2, lines 22-43).

It would have been obvious to one of ordinary skill in the art to incorporate freeze drying as taught by Iwata et al into the method of Chu because Iwata et al teaches that freeze drying thoroughly removes water from the carrier and Iwata et al also teaches that this provides for a test strip which provides high sensitivity and high accuracy measurement and excellent storage stability.

11. Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chu (US 6,284,194) in view of Yamamoto et al (US 6,117,289) as applied to claims 1-14, 16-45, 49-55, and 57- 62 above, and further in view of Iwata et al (US 5,912,139).

See above for teachings of Chu and Yamamoto et al.

Chu and Yamamoto et al differ from the instant invention in failing to teach the reactive layer is dried by freeze drying.

Iwata et al disclose producing a test strip by impregnating a carrier with a solution comprising components. Iwata et al disclose that the impregnated carrier is then dried by freeze drying (col 6, lines 48-59). Iwata et al disclose that the components can be surfactants (col 6, lines 3-14 and col 10, lines 10-22). Iwata et al disclose that freeze drying thoroughly removes water from the carrier (col 6, line 53). Iwata et al disclose that this provides for a test strip, which provides high sensitivity and high accuracy measurement and excellent storage stability (abstract & col 2, lines 22-43).

It would have been obvious to one of ordinary skill in the art to incorporate freeze drying as taught by Iwata et al into the modified method of Chu because Iwata et al teaches that freeze drying thoroughly removes water from the carrier and Iwata et al

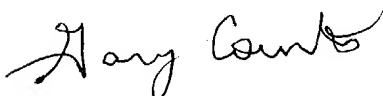
also teaches that this provides for a test strip which provides high sensitivity and high accuracy measurement and excellent storage stability.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Gary Counts
Examiner
Art Unit 1641
June 25, 2004



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